

**REMARKS**

Upon entry of the above amendment, claims 1-5, 7, 11, 17 and 18 are pending in the present application. Applicants cancelled claims 6 and 12-16 without prejudice to the subject matter contained therein. Applicants amended claims 1, 2, 4, 5, 7, 11 and 17 to more clearly define the present invention. Applicants added new claims 19 and 20 which are supported in original claims 1 and 5. The specification provides support for the amendments and no new matter has been introduced by the instant amendments.

**Election/Restrictions**

The Examiner has rejected Applicants' argument and has maintained the restriction requirement. Applicants amended claims 1, 4 and 5 to bring the claims in alignment with the elected subject matter.

**Claim Rejection under 35 U.S.C. § 112, first paragraph**

Claims 8, 9, 11 and 13-15 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains to make and/or use the invention. The Examiner argues that method claims are not adequately enabled solely based on the inhibition of Chemokine receptors provided in the specification. Applicants respectfully disagree; however in order to expedite prosecution, applicants cancelled claims 8-10 and 13-15 without prejudice to the subject matter contained therein, and amended claim 11 to the method of treating a disease selected from the group consisting of rheumatoid arthritis, multiple sclerosis, Chronic Obstructive Pulmonary Disease, psoriasis, dermatitis and uveitis. Supports to these amendments can be found for example on page 192 of the specification.

The test of enablement is whether one reasonably skilled in the art, following the teaching of the patent specification coupled with information known in the art at the time the patent application was filed, could make or use the invention without undue experimentation. *U.S. v. Teletronics Inc.*, 857 F. 2d 778, 8 U.S.P.Q.2d 1217 (Fed. Cir. 1998). Undue experimentation is experimentation that would require a level of ingenuity beyond what is expected from one of ordinary skill in the field. *Field v. Conover*, 170

U.S.P.Q. 276, 279 (C.C.P.A. 1971). *In re Wands*, 8 U.S.P.Q. 2d 1400, 1404 (Fed. Cir. 1988) and *In re Jackson*, 217 U.S.P.Q. 804, 807 (1982). A patent application, which contains a teaching of how to make and use the invention, must be taken as enabling unless there is a reason to doubt the truth of the teachings. *In re Marzocchi*, 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971).

Applicants provide guidance on pages 190-191 of the specification on how to test the compounds in CCR1 assays and applicants provided in vitro data. Based on these data, the disclosure of the specific diseases and the state of the art at the time of filing, Applicants asserts that that a skilled artisan in medicinal or pharmaceutical chemistry could use the compounds of this invention for the diseases listed in amended claim 11.

Applicant respectfully requests withdrawal of the 35 U.S.C. §112, first paragraph rejection.

#### Claim Rejection under 35 U.S.C. § 112, second paragraph

Claims 1-18 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention.

The Examiner rejected the term "carbonyl", "sulfur", "sulfonyl", "sulfinyl" and "oxy" as being vague and indefinite because they are divalent radicals. Applicants disagree that the terms are vague and indefinite. Applicants have indicated the substituent which is present on these radical in order to meet the last valency. The terms are also defined on pages 8 and 9 of the specifications. However, in order to expedite prosecution, Applicants amended the claims 1, 2, 4 and 5 to incorporate the definition of the term oxy, carbonyl and sulfur and to more clearly define their substitution, which allows to meet the desired valency.

The term "oxy" is defined to be hydroxy or  $-O-$  wherein the substituent on the oxygen is also defined in claim 1. The term "sulfur" is defined on page 9 to include  $-S-$ , sulfinyl  $-S(O)-$  and sulfonyl  $-S(O)_2-$  and the substituent on sulfur, sulfinyl and sulfonyl is also defined in claim 1. The substituent meets the last valency of the divalent species. The term carbonyl is also defined on page 9 to be  $-C(O)-$ , a divalent moiety which is substituted by a substituent defined in claim 1.

The Examiner objected to the phrases "for example" and "e.g.". Applicants deleted these phrases in claims 1, 4 and 5, therefore rendering the rejection moot.

The Examiner rejected the range R1-R4 and R'1-R'4 in claims 1 and 5 as being vague and indefinite. Applicants amended claims 1 and 5 to read R1, R2, R3 and R4 and R'1, R'2, R'3, R'4 respectively.

The Examiner rejected the limitation of claims 1 and 4 in the definition of Q and Q' being respectively CH, for having insufficient antecedent basis. Applicants amended the clerical error in claims 1 and 4 to Q and Q' being CH2.

The Examiner rejected the limitation "amide, guanidine, sulfonyl, sulfonamide and heterocycloalkyl" in the definition of R1 in claim 2 as lacking antecedent basis. Applicants respectfully disagree. In claim 1, R1 is defined as being a substituted carbonyl group (the carbonyl being defined as -C(O)- on page 9 of the specification), which carbonyl is substituted with amino, and which amino can be further substituted with alkyl. Therefore the amide group such as for example C(O)NH<sub>2</sub> or C(O)-N(alkyl)<sub>2</sub>, or C(O)NH-alkyl, has antecedent basis in claim 1.

Similarly, the term "sulfonyl" has antecedent basis in claim 1. "Sulfur" is defined on page 9 to include sulfonyl group -S(O)<sub>2</sub>- and to be substituted with a substituent also clearly defined in claim 1, such as, for example alkyl etc...Therefore a sulfonyl such as, for argument purpose, SO<sub>2</sub>alkyl has antecedent basis in claim 1.

The term "sulfonamide" such as for example -S(O)<sub>2</sub>NH<sub>2</sub> or -S(O)<sub>2</sub>NH-alkyl; has sufficient antecedent basis in claim 1. R1 is defined to be a substituted "sulfur" which can be substituted with amino and the amino is optionally substituted with alkyl etc..."Sulfur" is further defined so that it includes substituted -S(O)<sub>2</sub>- radical. Applicants assert that sulfonamide has antecedent basis in claim 1.

Applicants deleted the term "guanidine".

Finally, the term "heterocycloalkyl" is listed in the definition of R1 in claim 1 (the 10<sup>th</sup> variable for R1 in amended claim 1) and therefore as antecedent basis.

The Examiner rejected claim 7 and claims dependent thereon as being vague and indefinite in that it is unknown what is meant by Formula I, Ia, II, Ib or IIb. Applicants amended claim 7 to delete Formula Ib and IIb and included the phrase "as defined in

claims 1, 4, 5 respectively" to more clearly refer to Formulae I, Ia and II in the corresponding claims.

The Examiner rejected claims 8, 9, 13 and 16 as being substantial duplicates of claim 1 and rejected claims 10, 12 as being substantial duplicates of claim 7. Applicants cancelled claims 8, 9, 10, 12, 13 and 16 without prejudice to the subject matter contained therein; therefore the rejection is rendered moot.

The Examiner rejected claim 11 as being vague and indefinite as allegedly being unclear as which diseases are associated with Chemokine receptors. Applicants respectfully disagree, however in order to expedite prosecution, Applicants amended claim 11 to include specific diseases. Support is found in the specification on page 192.

The Examiner rejected claims 12, 14 and 15 as being indefinite for providing the use of a compound without setting forth any steps involved in the process. Applicants cancelled claims 12, 14 and 15 without prejudice to the subject matter contained therein, therefore the rejection is rendered moot.

The Examiner rejected claim 17 as being vague and indefinite in that it is not known what is meant by the variables R1, R2, R3, Y, Z, Q and R4 in the various formulae IV, V, X and XII. Applicants amended the dependency of claim 17 and added the phrase "wherein the substituents of Formulae IV, V, X and XII are as defined in Formula I of claim 1" for the corresponding substituents". The Examiner also rejected claim 17 as being vague and indefinite in that it is not known what is meant by formula II, Ia, Ib or IIb. Applicants deleted these formulae from claim 17.

All the other rejections raised by the Examiner under 35 U.S.C. § 112, second paragraph with respect to claim 17 have been rendered moot by deletion of terms and/or phrases.

Applicant respectfully requests withdrawal of the 35 U.S.C. §112, second paragraph rejection.

Claim rejection under 35 U.S.C. § 101

Claims 12, 14 and 15 stand rejected under 35 U.S.C. § 101 because the claimed recitation of use, without setting forth any steps involved in the process, results in an improper definition of a process. Applicants cancelled claims 12 to 15 without prejudice to the subject matter contained therein, therefore rendering the claim rejection moot.

Applicant respectfully requests withdrawal of the 35 U.S.C. § 101 rejection.

Conclusion

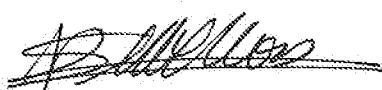
Applicants have addressed each and every issue set forth by the Examiner. Applicants submit that the claims are in good condition for allowance.

If the Examiner believes for any reason that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (617)871-5027.

If necessary, the Commissioner is hereby authorized in this, concurrent, and further replies, to charge payment or credit any overpayment to Deposit Account No. 50-4409 for any additional fees under 37 C.F.R. 1.16 or under 37 C.F.R. 1.17; particularly extension of time fees.

Respectfully submitted,

Novartis Institutes for BioMedical Research, Inc.  
220 Massachusetts Ave.  
Cambridge, MA 02139  
  
(617) 871-5027

  
\_\_\_\_\_  
Sophie Binet Cross  
Agent for Applicant  
Reg. No. 59,494

Date: March 2, 2010